

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Nov 17 2003

Image  
1642

Patent & Trademark Office

the Application of:

Name: Ledbetter *et al.*

Serial No.: 10/053,530

Filed: January 17, 2002

For: BINDING DOMAIN  
IMMUNOGLOBULIN FUSION  
PROTEINS

Group Art Unit: 1642

Examiner: Helms, Larry Ronald

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(c)

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the Applicants' duty under 37 CFR § 1.56, the following information is brought to the attention of the Examiner. The patents are listed on the attached Form SB08B and copies are enclosed for the convenience of the Examiner.

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 CFR § 1.56 and the submission thereof by Applicants shall not be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

The filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information, as defined in 37 CFR § 1.56, exists.

11/20/2003 CNGUYEN 00000038 024553 10053530

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(37 C.F.R. Section 1.8A)

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Nov. 11, 2003

Date of Deposit

Barbara J. Kiel  
Name of Person Mailing Paper

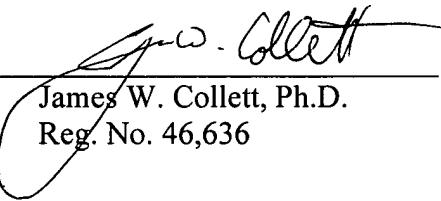
Barbara J. Kiel  
Signature of Person Mailing Paper

The attached Information Disclosure Statement is being filed in accordance with 37 CFR §§ 1.97(c) and 1.98. This Information Disclosure Statement is being filed after an action on the merits but before a Final Action under §1.113 or a Notice of Allowance under §1.113.

In the event that this Information Disclosure Statement is not received before a Final Action under §1.113 or a Notice of Allowance under §1.311, the Applicants respectfully request the filing of these papers to be considered a petition requesting consideration of this Information Disclosure Statement pursuant to 37 CFR §1.97(d).

The fee of \$180.00, pursuant to 37 CFR §1.17(p) is due in connection with this filing. The Commissioner is authorized to debit this amount and any additional fees required by this paper to Deposit Account No. 02-4553.

Respectfully submitted,

By: 

James W. Collett, Ph.D.  
Reg. No. 46,636

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Substitute for form 1449/PTO		Complete if Known			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		Application Number	10/053,530		
		Filing Date	1/17/03		
		First Named Inventor	Ledbetter		
		Art Unit	1642		
		Examiner Name	Helms, Larry Ronald		
Sheet 1	of 2	Attorney Docket Number	49076.000004.UTL2		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BREKKE et al., "The Structural Requirements for Complement Activation by IgG: Does It Hinge on the Hinge?", Immunol. Today 16:85-90 (1995)	
		BURKE et al., "Radioimmunotherapy for Acute Leukemia", Cancer Control, 9:106-113 (2002)	
		COLOMA, et al., "The Hinge as a Spacer Contributes to Covalent Assembly and Is Required for Function of IgG", J. Immunol. 158(2):733-40	
		DORAI, et al., "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human Immunoglobulin IgG1", Mol. Immunology 29:1487-1491 (1992).	
		DUNCAN, et al., "The Binding Site for Clq on IgG", Nature, 322:738-740 (1988)	
		GILLIES, et al., "Antigen Binding and Biological Activities of Engineered Mutant Chimeric Antibodies with Human Tumor Specificities", Hum. Antibodies Hybridomas 1:47-54 (1990)	
		ISENMAN, et al., "Correlation between the Exposure of Aromatic Chromophores ...", Biochemistry 16:233-240 (1977)	
		KLEIN, et al., "Expression of Biological Effector Functions by Immunoglobulin G Molecules Lacking the Hinge Region", Proc. Natl. Acad. Sci. USA 78:524-528 (1981)	
		MICHAELSEN, et al., "Antibody Dependent Cell-Mediated Cytotoxicity Induced by Chimeric Mouse-Human IgG Subclasses ...", Mol. Immunol. 29:319-326 (1992)	
		MICHAELSEN, et al., "Enhancement of Complement Activation and Cytolysis of Human IgG3 by Deletion of Hinge Exons", Scand. J. Immunol. 32:517-528 (1990)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:  
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Substitute for form 1449/PTO				C mplet if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Applicati n Num b r	10/053,530
				Filing Dat	January 17, 2002
				First Named Inventor	Ledbetter
				Art Unit	1642
				Examiner Name	Helms
Sheet 2	of 2	Attorney Docket Number	49076.000004.UTL2		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
		MICHAELSEN, et al., "One Disulfide Bond in Front of the Second Heavy Chain Constant Region...", Proc. Natl. Acad. Sci. USA 91:9243-9247 (1994).				
		NIKULA, et al., "Impact of the High Tyrosine Fraction in Complementarity Determining Regions: ....", Mol. Immunol. 32:865-872 (1995)				
		REDPATH, et al., "The Influence of the Hinge Region Length in Binding of Human IgG to Human Fcy Receptors", Hum. Immunol. 59:720-727 (1998)				
		SMELLIE, et al., "Radioimmunotherapy of Breast Cancer Xenografts with Monoclonal Antibody ICR12 ...", Cancer Res. 55:5842s-5846s (1995)				
		TAN, et al., "Influence of the Hinge Region on Complement Activation, C1q Binding, and Segmental Flexibility in Chimeric Human Immunoglobulins", PNAS, USA, 87(1):162-6				
		TAO, et al., "Role of Carbohydrate in the Structure and Effector Functions Mediated by the Human IgG Constant Region", 1989, J. Immunol. 143(8):2595-601)				
		THOMMESEN, et al., "Lysine 322 in the Human IgG3 CH2 Domain Is Crucial for Antibody Dependent Complement Activation", Mol. Immunol., 37:995-1004 (2000)				
		VAN DEN ABEELE, et al., "Antigen-Binding Site Protection During Radiolabeling Leads to a Higher Immunoreactive Fraction", J. Nucl. Med. 32:116-122 (1991)				
		WALKER, et al., "Aglycosylation of Human IgG1 and IgG3 Monoclonal Antibodies Can Eliminate Recognition by Human Cells ...", 1989, Biochem. J. 259(2):347-53)				
		ZHOROV, et al., "Oxidative Iodination of Rabbit IgG: Localization of the Label in the Fc Fragment and Modification Effects", Biokhimiia 56:828-838 (1991)				

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
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# FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$)**180.00**

<i>Complete If Known</i>	
Application Number	10/053,530
Filing Date	11/17/02
First Named Inventor	LEDBETTER
Examiner Name	HELM
Art Unit	1642
Attorney Docket No.	49076.001104. UTZ2

### METHOD OF PAYMENT (check all that apply)

Check  Credit card  Money Order  Other  None

Deposit Account:

Deposit Account Number: **02-4553**  
Deposit Account Name: **BUCHANAN INGERSOLL PC.**

The Commissioner is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) during the pendency of this application  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

### FEE CALCULATION

#### 1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 740	2001 370	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 510	2003 255	Plant filing fee	
1004 740	2004 370	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
<b>SUBTOTAL (1) (\$)</b>			

#### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
	-20**	= <input type="text"/> X <input type="text"/> = <input type="text"/>	
Independent Claims	- 3**	= <input type="text"/> X <input type="text"/> = <input type="text"/>	
Multiple Dependent		= <input type="text"/>	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
<b>SUBTOTAL (2) (\$)</b>		

*\*\*or number previously paid, if greater; For Reissues, see above*

### FEE CALCULATION (continued)

#### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 400	2252 200	Extension for reply within second month	
1253 920	2253 460	Extension for reply within third month	
1254 1,440	2254 720	Extension for reply within fourth month	
1255 1,960	2255 980	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,280	2453 640	Petition to revive - unintentional	
1501 1,280	2501 640	Utility issue fee (or reissue)	
1502 460	2502 230	Design issue fee	
1503 620	2503 310	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 740	2809 370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	
1801 740	2801 370	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	
Other fee (specify) _____			
*Reduced by Basic Filing Fee Paid			
<b>SUBTOTAL (3) (\$)</b>			180.00

(Complete if applicable)

Name (Print/Type)	<b>JAMES W. COLLETT</b>	Registration No. (Attorney/Agent)	46,636	Telephone 619.578.5010
Signature	<i>J. W. Collett</i>			Date 11/10/03

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

		Application Number	10/053,530
		Filing Date	1/17/02
		First Named Inventor	Ledbetter
		Art Unit	1642
		Examiner Name	Helms
Total Number of Pages in This Submission	5	Attorney Docket Number	49076.000004.UTL2

ENCLOSURES (Check all that apply)			
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <i>(2 pages)</i> <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): PTO-SB08B with 20 references and Return Postcard	Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	James W. Collett
Signature	
Date	November 11, 2003

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Barbara J. Kielt
Signature	
	Date Nov. 11, 2003

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**SERIAL NO.:** 10/053,530

**FILED:** 1/17/02

**ATTORNEY:** Bradford J. Duft

**DATE OF MAILING:** November 11, 2003

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**BINDING DOMAIN IMMUNOGLOBULIN  
FUSION PROTEINS**

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**DOCKET NO.:** 49076.000004.UTL2

**ENCLOSURE(S):** Transmittal Form; Fee Transmittal  
for FY 2003 (2 copies); PTO-SB08B with 20 references  
and Return Postcard